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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,677	03/25/2004	Francis C. Wessling, JR.	322101.1030	6200

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EXAMINER

MCCRAW, BARRY CLAYTON

ART UNIT PAPER NUMBER

3744

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/808,677	Applicant(s) WESSLING, ET AL.	
	Examiner B. Clayton McCraw	Art Unit 3744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 17-21 is/are rejected.
- 7) ☒ Claim(s) 15 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/29/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 10-12, 14, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson (US 4,191,125). Johnson explicitly teaches the method and apparatus of a phase change material having a selectable phase change temperature in a range between approximately zero degrees Celsius and four degrees Celsius (col. 2, lines 57-69) comprising a mixture of water and deuterium oxide (col. 2, line 59) wherein a mole fraction of deuterium oxide is selected to provide a desired phase change temperature (col. 2, lines 57-60), a nucleating agent being added to the mixture (col. 2, lines 38-44), adding a colorant to the mixture (col. 3, lines 12-23), and storing a temperature sensitive material in an environment requiring temperatures between approximately zero degrees Celsius and four degrees Celsius (col. 1, lines 5-10 and col. 3, lines 6-23), a pack for holding the phase change material (col. 2, lines 33-37) wherein the pack is shaped to conform for a desired treatment (Figure 1, item 3; "ampule" shaped as a freeze indicator), the sensitive material thermally isolated from the environment (col. 1, lines 6-19), and wherein the sensitive material is a biomaterial (col. 2, lines 46-63).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 4, 13, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (US 4,191,125) in view of Douglas-Hamilton (US 4,530,816). Johnson teaches the elements of the invention as described above, but fails to teach a gel material added to the mixture. Douglas-Hamilton explicitly teaches a gel material added to the mixture (col. 2, lines 66-67). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the phase change material of Johnson with the gel material of Douglas-Hamilton because adding gel to a thermal mixture increases the thermal capacity of the mixture.

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6. Claim 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (US 4,191,125) in view of Hjertstrand et al. (US 4,145,895). Johnson teaches the elements of the present invention as described above, but does not teach a temperature depression material, placing the phase change material in close proximity to a sensitive material so that the temperature of the sensitive material is maintained near the temperature of the phase change material, or providing a container for holding the sensitive material. Hjertstrand et al. explicitly teach placing a temperature depression material (col. 5, lines 17-20, "salt solutions") phase change material (comprising water and deuterium oxide) in close proximity to a sensitive material so that the temperature of the sensitive material is maintained near the temperature of the phase change material (col. 2, lines 66-68 and col. 3, lines 1-10) and providing a container for holding the sensitive material (Figure 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the phase change material of Johnson with the container of Hjertstrand et al. because deuterium oxide enables the container to maintain the specific temperature range of approximately 0-5 degrees Celsius.

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (US 4,191,125). Johnson teaches the elements of the present invention as described above, but does not teach the material used as a treatment pack. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations.

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Allowable Subject Matter

8. Claim 15 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Clayton McCraw whose telephone number is (571) 272-3665. The examiner can normally be reached on M-F 8:30AM-5:00PM.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cheryl Tyler can be reached on (571) 272-4834. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



BCM
5/30/2006



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